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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,339	06/18/2007	Robert L. Wolfert	DEX0531US.NP	8696
32800	7590	09/18/2009	EXAMINER	
LICATA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053			HAQ, SHAFIQUL	
			ART UNIT	PAPER NUMBER
			1641	
			NOTIFICATION DATE	DELIVERY MODE
			09/18/2009	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

poreilly@licataandtyrrell.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/588,339	<b>Applicant(s)</b> WOLFERT ET AL.	
	<b>Examiner</b> SHAFIQUL HAQ	<b>Art Unit</b> 1641	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 August 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) 1-4,8-9,12,17,19,22,25-27,35-36,39,42-45,48,51-52,55,59,61,64,67-70,73-74,76,78,80-82 and 86-89 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-4,8-9,12,17,19,22,25-27,35-36,39,42-45,48,51-52,55,59,61,64,67-70,73-74,76,78,80-82 and 86-89 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121 and 372:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted. The various invention groups are as follows:

- I. Claims 1-4, 8-9, 12, 17, 19 and 22, drawn to a method for measuring enzymatically active lipoprotein-associated phospholipase A2.
  - II. Claims 25-27, 30, 35-36, 39, 42-45, 48, 51-52, 55, 59, 61, 64 and 67-70, drawn to a method and a kit for measuring enzymatically active lipoprotein-associated phospholipase A2.
  - III. Claims 73-74, 76, 78, 80-82 and 86-89, drawn to a method and a kit for measuring enzymatically active lipoprotein-associated phospholipase A2.
2. The invention groups listed in groups I-III do not relate to a single general inventive concept under PCT rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reason :

The special technical feature i.e. "contacting immobilized Lp-PLA2 with a substrate to convert to detectable product" of the invention Groups I-III, is obvious over Kujiraoka *et al* (Journal of lipid research 2003) in view of Kosaka *et al* (Clinica Chimica Acta 2000). Kujiraoka *et al* disclose detection of PAF-AH (also known as

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Lp-PLA2) in a sample using immobilized monoclonal antibody on microtiter plate (see “measurement of plasma total PAF-HA concentration” in page 2008). PAF-HA that is bound to monoclonal antibody is then detected by biotinylated second antibody. Kujiraoka *et al* fail to disclose using substrate of PAF-HA for spectrometric detection. However, Kosaka *et al*, in a spectrophotometric assay for detection of PAF-AH (pages 151-155), disclose several PAF analogues containing 4-nitrophenyl groups as substrates for PAF-HA (see page 154) that read on the substrates of claims 8, 51 and 68 of present application. Kosaka *et al* also disclose that PAF-HA activity is related to atherosclerotic diseases. Therefore, considering the fact that substrate for PAF-AH (Lp-PLA2) is common and known in the art (Kosaka *et al*), it would have been obvious at the time of the invention to a person of ordinary skill in the art to substitute biotinylated second antibody of Kujiraoka *et al*, with PFA-HA substrates (as disclosed by Kosaka *et al*) in the method of Kujiraoka *et al*, with the expectation of similarly detecting/monitoring PAF-AH (Lp-PLA2) activity in a sample with a reasonable expectation of success.

Consequently, the special technical feature which links claims of groups I-III, does not provide a contribution over the prior art. As MPEP 1893.03(d) notes “The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art.” In current case, Groups I-III s drawn to “drawn to a method for measuring enzymatically active lipoprotein-associated phospholipase A2”, but the groups do not make a contribution over the prior art because the special technical

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feature (i.e. contacting immobilized Lp-PLA2 with a substrate to convert to detectable product) that links the group is obvious over the prior art references as described above. Therefore, invention groups I-III are not so linked as to form a single general inventive concept and the lack of unity requirement is proper.

3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).
4. The election of the invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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5. Furthermore, this application contains claims that are generic to multiple patentably distinct polymer of “poly(amidoamine) dendrimer”, “peptide” and “oligonucleotide” encapsulating a noble metal.

Therefore, in the event of election of either one of the group I-III, Applicants are required in accordance with the practice set forth in MPEP 803.02, to elect

1) a single species of a “binder” and

2) a single species of a “substrate”, including an exact definition of each substitution on the base molecule, wherein a single member at each substituent group or moiety is selected.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Chemical structures, which are similar, are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrefutable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holding of Application of Papesch, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and In re Laly, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are patentably distinct where the structures are either not structurally similar, or the prior art fails to

suggest a function of a claimed compound would have been expected from a similar structure.

**Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.**

There is an examination and search burden for these patentability distinct species due to their mutually exclusive characteristics. The species require different field of search (e.g. searching different classes/subclasses or electronic resources, or employing different search queries); and/or the species are likely to raise different non-prior art issues under 35 U.S.C 101 and/or 35 U.S.C 112, first paragraph.

Upon the election of a single disclosed compound (e.g. Example, page number and structural depiction), the scope of the invention, inclusive of the elected compound, will be identified by the Examiner for examination along with the elected species. Moreover, whatever specific compound is ultimately elected, applicants are required to list all claims readable thereon. In the instant case, upon election of a single compound, the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound (compounds which are so similar thereto as to be within the same inventive concept and reduction to practice). The scope of an independent invention will encompass all compounds within the scope of the claim, which fall into the same class and subclass as the elected compound, but may also include additional compounds, which fall in related subclasses. Examination will then proceed on the elected

compound AND the entire scope of the invention encompassing the elected compound will be determined.

All compounds falling outside the class(es) and subclass(es) of the selected compound and any other subclass encompassed by the election above will be directed to nonelected subject matter and will be withdrawn from consideration under 35 U.S.C. 121 and 37 C.F.R. 1.142(b). Applicant may reserve the right to file divisional applications on the remaining subject matter. (The provisions of 35 U.S.C. 121 applies with regard to double patenting covering divisional applications.)

If desired upon election of a single compound, **applicants can review the claims and disclosure to determine the scope of the invention and can set forth a group of compounds, which are so similar within the same inventive concept and reduction to practice.** Markush claims must be provided with support in the disclosure for each member of the Markush group. See MPEP 608.01(p). Applicant should exercise caution in making a selection of a single member for each substituent group on the base molecule to be consistent with the written description.

6. **Applicant is advised that a reply to this requirement to be complete must include (i) an election of a species to be examined** even though the requirement may be traversed (37CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.



The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traverse must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

7. The species described above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding technical features for the following reasons: Pursuant to PCT Rule

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13.2 and PCT Administrative instructions, Annex B, Part 1 (f)(I)(B)(2), the species are not art recognized equivalents.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143). Applicant is advised that a reply to this requirement must also include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.
9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(1)

### ***Conclusion***

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shafiqul Haq/

Primary Examiner, Art Unit 1641